

## **STATUS OF CLAIMS**

Claims 1-18 are pending.

Claims 1-18 stand rejected by the Examiner.

Claims 1 and 10 have been amended, without prejudice, herein.

Claims 19 and 20 have been newly added, herein.

## **REMARKS**

Reconsideration of the present Application is respectfully requested.

### **Response After Final**

Entry of this Response is respectfully requested on the ground that this Response places the application in condition for allowance. Alternatively, entry of this Response is respectfully requested on the ground that this Response places the claims in better form and condition for appeal. Furthermore, Applicant submits that any arguments or amendments made regarding the claims do not require an additional search on the part of the Office, nor do any arguments or amendments made herein raise new issues with regard to the patentability of the claims now pending.

### **Claim Rejections Pursuant to 35 U.S.C. §102(b)**

Claims 1 and 9 have been rejected under 35 U.S.C. §102(b) as being anticipated by Lewis et al. (U.S. Patent No. 6,392,327). Claims 10 and 18 have been rejected under 35 U.S.C. §102(a) as being anticipated by Jackson et al. (U.S. Patent No. 6,475,148). Applicant respectfully traverses these rejections for at least the following reasons.

35 U.S.C. §102 recites, in part:

A person shall be entitled to a patent unless-

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

Consistently, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See, M.P.E.P. §2131 citing Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).*

Applicant respectfully submits that the cited references do not teach each of the limitations of independent claims 1 or 10. Specifically, neither Lewis nor Jackson teaches at least a transdermal substance delivery device or method of transdermal substance delivery that includes a sensor for receiving ultrasonic transmissions that are reflected off of either the at least one substance or the tissue into which the substance is being moved through.

The present invention as claimed in amended independent Claim 1 uses at least one sensor ***to receive ultrasonic transmissions reflected off of either said tissue or said at least one substance.*** Applicant agrees with the Examiner that the sense elements of Lewis generate electrical signals in response to the mechanical displacement of the drive elements, as this is what Applicant expressed in response to the previous Office Action. However, Applicant respectfully submits the Examiner is overreaching in his assertion that Lewis somehow teaches the sense elements "sense" the ultrasonic transmissions via the operational changes sensed in the drive elements. Applicant notes that this assumes that the Examiner is correct in asserting that reflected ultrasonic

transmissions do in fact cause such operational changes in the drive elements. However, regardless of whether ultrasonic transmissions cause the listed operational changes (such as changes due to temperature variations, loading, stress, cracking or electrical inputs), this sensing is, at the very most, *indirect* sensing of ultrasonic transmissions. Just as Lewis explains, the sensors of Lewis *actually sense* changes to the operational characteristics of the drive elements. They do not sense ultrasonic transmissions, they sense temperature variations, loading changes, stress changes, cracking or electrical input changes. Applicant notes the sensor of the present invention is not structured to “ultimately determine the existence of reflected ultrasonic transmissions”. It is to actually sense ultrasonic transmissions, not mechanical effects on the transducer.

However, without agreeing to the Examiner’s interpretation of the teaching of Lewis, Applicant has nonetheless amended Claim 1 so that the sensor *receives* the reflected ultrasonic transmission. This is quite distinguishable from the sensor of Lewis, which only senses changes in the operational characteristics of the drive elements. Even if it is believed that such changes in the operational characteristics of the drive elements might be caused by reflected ultrasonic transmissions, *the sensors of Lewis do not actually receive these ultrasonic transmissions*, simply because the sensors of Lewis are designed to sense other features like temperature variations, loading changes, stress changes, cracking or electrical input changes.

Similarly, the present invention as claimed in amended independent Claim 10 uses at least one sensor to receive ultrasonic transmissions reflected off of either said tissue or said at least one substance. Also, Applicant has amended Claim 10 to reflect the transdermal delivery of at least one substance, not only in the preamble, but also in the body of the claim.

The method as taught by Jackson is for destroying microspheres, such as microbubbles, microparticles and contrast agents (Jackson at Col. 2, line 1), that are *introduced via intravenous*

*injection or injection into the bloodstream or tissue*, with the circulatory system carrying the microspheres to the region targeted for treatment (Jackson at Col. 3, lines 52-58). While the Examiner asserts that there are embodiments taught by Jackson involving drug delivery “adjacent to the tissue to be treated” (Office Action at page 5, last paragraph), and later that it actually teaches “transdermal delivery” (Office Action at page 7, last paragraph), no citation of just where Jackson teaches any such embodiment. As explained by Jackson, “The microspheres are introduced into the patient”, and also “Microspheres are provided within the patient by injection into the blood stream or tissue proximate to the region to be treated (Jackson at Col. 3, lines 52-58). These embodiments do not include transdermal delivery, and for that matter, it should be readily apparent that a *transdermal* push of a substance into tissue is not the same thing as *an injection* of microspheres into the body and the subsequent destruction of those microspheres to release the associated drug.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. 102(a) and (b) rejections of claims 1 and 10, as both Lewis and Jackson fail to teach the invention recited in claims 1 and 10, as amended. Further, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. 102(a) and (b) rejections of claims 9 and 18, as these claims ultimately depend from a patentably distinct independent base claim 1 or 10.

#### **Rejections based on 35 U.S.C. § 103(a)**

Claim 2 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, in view of Shimada et al. (U.S. Patent No. 5,267,985). Claims 3-8 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, in view of Dellagatta (U.S. Patent No. 5,954,675). Claim 11 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson, in view of Shimada. Claims 12-17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over

Jackson, in view of Dellagatta. Applicant respectfully traverses these rejections for at least the following reasons.

35 U.S.C. 103(a) sets forth in part:

[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

For at least the reasons stated above, the cited references, either separately or in any combination, do not teach or suggest each of the limitations of claims 1 or 10. Specifically, as previously explained, neither Lewis nor Jackson teaches at least a transdermal substance delivery device or method of transdermal substance delivery that includes at least one sensor for receiving ultrasonic transmissions reflected off of either said tissue or said at least one substance. Similarly, neither Shimada nor Dellagatta teach a transdermal substance delivery device or method of transdermal substance delivery that includes at least one sensor for receiving ultrasonic transmissions reflected off of either said tissue or said at least one substance, as such a sensor is

completely absent in the inventions of both Shimada and Dellagatta. Additionally, because of the complete absence of such a sensor, there is no suggestion or motivation to modify any single reference or to combine these reference teachings to meet such a limitation.

Accordingly, Applicant submits at least claims 1 and 10 are patentably distinguishable over the art of record. Applicant further submits that claims 2-9 and 11-18 are similarly distinguishable over the art of record, at least by virtue of their ultimate dependency from a patentably distinct base claim 1 or 10.

### **Newly Added Claims**

Applicant has added Claims 19 and 20, as none of the references teach having a control system that can measure the amount of the at least one substance delivered into the tissue, based on the reflected ultrasonic transmissions received by the at least one sensor. Support for these new claims can be found in the specification beginning at page 6, paragraph 27, wherein it states:

The electronic character of the echo pattern may measure the starting dosage amount within the TDD, and later compare that starting value to later values as the medicant is liberated from the TDD over time... The electronic character of this echo pattern may measure the dose which actually permeates the skin, and may later be compared to the electronic character signature starting value within the TDD to the later received values as the medicant is liberated from the TDD over time to calculate the quantity of medicant actually received by the patient at any particular point in time.

### **CONCLUSION**

Wherefore, Applicant believes that all outstanding grounds raised by the Examiner have been addressed and respectfully submits the present case is in condition for allowance, early notification of which is earnestly solicited. Should there be any questions or

outstanding matters, the Examiner is cordially invited and requested to contact Applicant's undersigned attorney at his number listed below.

Date: January 18, 2007

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Justin C. Allen", is written over a horizontal line.

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